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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/424,815	04/10/2000	PETRUS HENDRICUS NIBBERING	702-991768	8660

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EXAMINER
SNEDDEN, SHERIDAN

ART UNIT	PAPER NUMBER
1653	26

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/424,815	NIBBERING ET AL.	
	Examiner	Art Unit	
	Sheridan K Snedden	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-60* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *28-60* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The Restriction requirement of Paper No. 24, filed October 16, 2002 is withdrawn in view of the following. Claims 28-60 are pending.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 28-34, 46, 47, 55 drawn to peptide fragments and derivatives of SEQ ID NO: 1 possessing antimicrobial activity.

Group II, claim(s) 35-40, 48, 53, 54, drawn to a hybrid molecule comprising peptide fragments and derivatives of SEQ ID NO: 1 and an effector molecule.

Group III, claim(s) 41-43, 45, 47, 49 and 60, drawn to a method of treating infection with the molecules of Group I.

Group IV, claim(s) 44, drawn to a method of treating infection with the molecules of Group II.

Group V, claim(s) 50-51, 56-58, drawn to a method of labeling a cationic peptide.

Group VI, claim(s) 52 and 59, drawn to a method of making ubiquicidine.

3. Upon thorough consideration of the claims, the examiner has determined that a lack of unity of invention exists, as defined in Rule 13.

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the

same or corresponding special technical features. Annex B, Part 1(b), indicates that "special technical features" means those technical features which as a whole define a contribution over the prior art. The inventions listed as Groups I-VI are directed to peptide composition (or method of use or method of making thereof) that share the common special technical feature of fragments of the amino acid sequence of SEQ ID NO: 1. This common special technical feature is not a contribution over the prior art as it is taught by Japanese Patent 08176193 A (1996). Thus the invention of Groups I-VI lack unity of invention.

4. As the above groups lack unity of invention, Groups I-IV are patentably distinct for the following reasons:

The protein of invention I is related to the hybrid molecule of invention II by virtue of being a hybrid containing the protein of invention I. Although the protein and hybrid are related, they are distinct inventions because the protein can be used in another and materially different processes such as in the production of the antibody. Additionally, the protein of invention I would not render the hybrid molecule obvious. Thus, the invention of Groups I and II are patentably distinct.

Invention I is related to the inventions III, V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of invention I can

be used in a materially different process such as generating antibodies, or as in any one of inventions III, V and VI, for example.

Invention II is related to invention IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the hybrid molecule of invention I can be used in a materially different process such as generating antibodies.

The methods of inventions III-VI require different products and steps and have different endpoints. Therefore, inventions III-VI are patentably distinct.

The product of invention I is not used in the method of invention IV. Therefore, invention I is patentably distinct from invention IV.

The product of invention II is not used in the method of invention III, V and VI. Therefore, invention II is patentably distinct from invention III, V and VI.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-VI, restriction for examination purposes as indicated is proper.

5. Group I, Claims 28-34, 46, 47, 55 are generic to a plurality of disclosed patentably distinct species comprising the peptides of SEQ ID NO: 2-9, fragments comprising at least 3 amino acids form the sequence of SEQ ID NO: 1, and derivatives of the above peptides and fragments. Absent factual statement/evidence to the contrary, each different peptide sequence,

fragment and derivative is considered distinct and/or independent, one from the other on the basis of physical, chemical and biological properties and function(s). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Group II, Claims 35-40, 48, 53, 54 are generic to a plurality of disclosed patentably distinct species comprising a hybrid molecules between peptides comprising SEQ ID NO: 2-9, all fragments comprising at least 3 amino acids form the sequence of SEQ ID NO: 1, or derivatives thereof, and effector molecules comprising molecules that bind to micro-organisms or molecules that bind the molecules secreted by micro-organisms. Absent factual statement/evidence to the contrary, each different hybrid molecule is considered distinct and/or independent, one from the other on the basis of physical, chemical and biological properties and function(s). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Advisory Information

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-3975 for regular communications and (703) 746-3975 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
February 19, 2003
SKS

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER